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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,902	01/11/2001	Roberts S. David	PC9047D	1327

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

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12/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/758,902	DAVID ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-11-08 has been entered.

Claims 19 and 20 are under examination.

The art rejections of record are withdrawn in view of the new rejections set forth below based on Applicants amendment to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (The Veterinary Record, 120:435-439, 1987) in view of Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983), Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991).

Green et al teach the formulation of a three multivalent clostridial vaccines for the purposes of stimulating a protective immune response against multiple species and serotypes and species of this pathogen. Green et al teach three known commercially available vaccines comprising at least 8 different serotypes/species of Clostridium for protection from infection (Tasvax, Heptavac, Covexin) page 435, column 2, Table 1. In particular Covexin comprises four formal cultures (i.e. the instant bacterins) of four different species/serotypes of Clostridia, three toxoids from three different species/serotypes of Clostridia and a combination of toxoid + lysed cells from a seventh specie/serotype of Clostridia. (see Table 1, page 345). Green et al differ by not teaching the vaccine in combination with the adjuvant Saponin or with an antigen from a respiratory virus.

Seifert teaches the use of a saponin adjuvant in the formulation of a multivalent clostridial vaccine using toxins of different strains of Clostridial pathogens for the purposes of obtaining enhanced protective immune responses in a host.

Geresi et al teach the formulation of multivalent clostridial vaccine compositions Clostridium perfringens antigens (C and D-type toxins: different serotypes) and tetanus toxoid (different species), which also comprise a viral antigen (see page 38).

Farmers and Consumers Market Bulletin disclose a clostridial vaccine composition which comprises a viral immunogen from influenza, equine viral rhinopneumonitis, strangles and teaches the annual vaccination with the multivalent vaccine reduces the threat of infection from both the bacterium and the virus.

Kensil et al show the use of a saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprises a viral antigen. Kensil establishes the adjuvant activity of saponin is effective for viruses.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify any of the commercially available Clostridial bacterin-toxoid vaccines of Green et al by adding any further desired additional viral

component as taught by Geresi and Farmers and Consumers Market Bulletin to include a respiratory viral antigen as taught by Farmers and Consumers Market Bulletin because Geresi and add the adjuvant saponin to the combined Clostridial bacterin-toxoid viral antigen composition because the art teaches that it is conventional to combine the multivalent clostridial vaccines with viral components and both Seifert and Kensil teach the use of saponin as an effective adjuvant for the enhancement of an immune response with either a clostridial or viral antigen respectively therefore the vaccine as combined would provide the art recognized advantages of reduced time and cost for administering multiple vaccines to farm/ranch animals. Absent unexpected results, one of skill in the art would expect the modified composition to protect from infection because the saponin adjuvant was effective to generate protective immunity in cattle and that similar compositions with additional or substituted adjuvants were also effective to generate immunity in farm animals.

The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See *In re Rosselet,* 146 USPQ 183, 186 (CCPA 1965). "There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997). An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Applicant's arguments have been fully considered to the extent that they are pertinent to the recast rejection but are still not persuasive. Applicant argues that that Seifert does not teach a multicomponent Clostridial vaccine, that all the antigens are toxoids and that saponin is the sole plant derived adjuvant. This is not persuasive in view of the new rejection of record that modifies any one of three different multicomponent bacterin-toxoid vaccines known to the art at the time the invention was made. All of Applicants arguments are moot, because Seifert et al is not relied upon for the bacterin components and is relied upon for its use of saponin. Further, Seifert et al teach the general use of the method for Clostridia toxoid production and combination of toxoids with saponin in general (pages 16-17) and is not limited to argued strain 217. Applicants argue that Geresi et al teach that the combination of *C. perfringens* antigens depressed the value of immunity-degree developed after the introduction of the combined antigens. This is not persuasive because in the next paragraph Geresi et al specifically teach that antigenic competition can be mitigated with the use of whole cell immuno-modulants even in the case of a combination of six antigens. The combination provides for whole cell (bacterin) immuno-modulants. Even if this was not noted by Geresi et al, a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Obviousness does not require absolute predictability of success. For obviousness, all that is required is a reasonable expectation of success. *In re O'Farrell* 853 F.2d 8894, 7 USP2d 1673 (Fed Circ. 1988). Here, multiple different combinations of toxoids and bacterins were known to the art, the combination of different toxoids with viral antigens were known to be effective, the combination of such is obvious and combination with saponin, a known adjuvant effective for viral and clostridial toxoids is obvious. Applicants argue that the references do not provide explicit motivation to combine. This is not persuasive because explicit motivation recited in the cited references is not required and motivation to make the combination has been provided.

Further, the composition is merely a combination of known prior art elements useful for vaccination assembled according to known methods to yield predictable vaccination results.

Status of the Claims

Claims 19 and 20 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner